PROVIDER REIMBURSEMENT REVIEW BOARD HEARING DECISION

99-D70

PROVIDER - County of Los Angeles/ Department of Health Services

DATE OF HEARING- June 4-5, 1996

Provider No. 05-0040 & 05-0373
05-0376 & 05-0578

Cost Reporting Period Ended -
June 30, 1981
June 30, 1982
June 30, 1983

vs.

INTERMEDIARY -Blue Cross and Blue Shield Association/Blue Cross of California

CASE NO. 92-0110G

INDEX

ISSUE:

Were the pre-composite rate End Stage Renal Disease ("ESRD") screens invalid and therefore not applicable to limit the Provider's reimbursement for ESRD treatments?

STATEMENT OF THE CASE AND PROCEDURAL BACKGROUND:

Los Angeles County public hospitals ("the Providers") comprise a group of four providers located in Los Angeles California. The Providers' fiscal intermediary is Blue Cross of California ("Intermediary"). The fiscal periods at issue are June 30, 1981, 1982, and 1983.[1] The parties stipulate that the issue before the Provider Reimbursement Review Board ("Board") is purely legal and that there are no facts in dispute. They call upon the Board to decipher the legality of the ESRD pre-composite rate screens.

Legislative History of the ESRD Pre-Composite Rate Screens:

During the cost reporting years at issue, the Providers were reimbursed by Medicare for the reasonable costs incurred for the provision of services to Medicare beneficiaries. Title XVIII of the Social Security Act, section 1861, codified at 42 U. S. C. § 1395x(v)(1)(A)et seq. The regulations implementing this statute appear at 42 C.F.R. § 405.451 (redesignated at § 413.9, 1986).

In October 1972, Congress established the ESRD program by extending Medicare coverage to insured individuals who required hemodialysis or renal transplantation for this disease. Social Security Act Amendments of 1972, Pub. L. No. 92-603, § 2991, 1972 U.S.C.C.A.N. (Stat.) 1463, 1713 (codified at 42 U.S. C. § 426(e), (f), and (g). The pertinent section of the statute for purposes of this appeal was to be in effect on July 1, 1973 and read, "the Secretary [of Health and Human Services ("Secretary")] is authorized to limit reimbursement under Medicare for kidney transplant and dialysis to kidney disease treatment centers that meet such requirements as he may by regulation prescribe . . ." 42 U. S.C. 426(e), (f), and (g).

The implementing regulations for the ESRD program were designated as "interim" regulations and implemented without notice and comment. 38 Fed. Reg. 17,210 (June 29, 1973) to be codified at 42 C.F.R. § 405.402(g). In pertinent part the preamble to that regulation reads,

---

[1] This case originally also concerned fiscal years ended 6/30/76 and 6/30/78 through 6/30/80. However, prior to the hearing on June 4, 1996, the Providers and the Intermediary agreed to settle the FYE 6/30/78 through 6/30/80 appeals through an administrative resolution, and it was determined that FYE 6/30/76 had been mistakenly included. Thus, FYE 6/30/76 is no longer at issue.

> The legislation authorizes the Secretary to limit reimbursement as he may prescribe by regulation. In view of the new issues that stem from the virtually universal coverage of a very complex service, the absence of prior experience, and possible precedents that the regulation may establish, final decisions on Medicare payment and facility qualification policies will require careful study and reevaluation based on operating experience. Operations on July 1, 1973 are to be based on interim regulations.... In addition, interim reimbursement levels and mechanisms to be employed should not be construed to reflect the final policies which will be adopted and which are expected to contain additional features providing incentives for effective and efficient performance. During the interim period, limits will be applied to reimbursement amounts and services covered beyond which payment will be made, i.e., will be considered reasonable and necessary, only if adequate justification is provided.....

42 C.F.R. 405.402(g).

Next, the Bureau of Health Insurance ("BHI"), predecessor to the Health Care Financing Administration ("HCFA") issued Intermediary Letters ("IL") stating the interim policies and procedures concerning chronic renal disease.[2] The letters issued on June 29, 1973, were effective July 1, 1973, and established specific dollar limits of $150 and $145[3] to all provider and nonprovider facilities rendering ESRD services. See IL Part A 73-25 and Part B 73-22. A year later, another IL was issued altering the reimbursement rate to $138 per treatment. This is the rate in dispute in this appeal. See IL Part A 74-26 and Part B 74-24 (August 1974). The interim reimbursement screens remained in effect until the establishment of the composite rate reimbursement system in August 1983. 48 Fed. Reg. 21,254 (May 11, 1983).[4]

Litigation ensued over the subject ESRD screens, specifically the Schupak v. Mathews decision wherein the federal District Court for the District of Columbia invalidated the 1973 IL in an action brought by a non-provider. First the court found that the ESRD reimbursement policies set forth in the 1973 IL constituted substantive rules not promulgated in accordance with the Administrative Procedure Act ("APA"). The court went on to invalidate the 1973 IL "insofar as it imposes a formula for the calculation of an estimated customary charge for nonproviders under the chronic renal disease

---

[2] Intermediary letters are guidelines for fiscal intermediaries that govern reimbursement practices.

[3] $ 145 was paid when the lab was billed separately.

[4] See Part A IL 75-19 (May 1, 1975) extending interim ESRD screens to July 1, 1976 and Part A IL 77-35 (November 1977) extending ESRD screens indefinitely.

Medicare program." Schupak v. Mathews, [1976 Transfer Binder] Medicare & Medicaid Guide (CCH) 27,987, at 10,007 (D.D.C. Sept. 17, 1976), aff'd unpublished order (D.C. Cir. 1997). On June 13, 1978, Congress enacted the End Stage Renal Disease Program Improvements. Pub. L. No. 95-292, 1978 U.S.C.C.A.N., 92, Stat. 307, codified at 42 U.S.C. § 426-1, 1395rr. This amendment expressly repealed section 2991 and mandated that HCFA determine the amount of payment for ESRD services under Part A of the Medicare program "in accordance with section 1861(v). This section requires regulations to establish the methods used in setting limits on.... costs ... of specific items or services to be recognized as reasonable....." 42 U.S.C. § 1395x(v)(1)(A). With respect to Part B services, the 1978 Act required HCFA to establish regulations for payments to providers for ESRD services, which were to set forth:

> methods and procedures to (i) determine the costs incurred by providers of services and renal dialysis facilities in furnishing covered services to individuals determined to have end-stage renal disease, and (ii) determine, on a cost-related basis or other economical and equitable basis (including any amount authorized under section 1861 (v)), the amounts of payments to be made under Part B services furnished by such providers and facilities to such individuals.

codified at 42 U.S.C. 1395rr (b) (2) (B) et seq.

PROVIDERS' CONTENTIONS:

The Providers challenge the pre-composite rate ESRD screens on three primary grounds. First the Providers contend that the screens were established without notice and comment violating the procedural requirements of the APA. Second, the 1973 interim regulation was without statutory authority when promulgated and was expressly repealed, and thus invalid with the enactment of the 1978 Act. Finally, the Providers assert that the screens were established in a manner that was arbitrary, capricious, an abuse of discretion, and contrary to the law and therefore, violated the substantive requirements of the APA.

With respect to the Providers' contention that the screens violated the procedural requirements of the APA, the Providers argue that the Intermediary Letter established the screens without the required notice and comment, and as such, are invalid. 5 U.S.C. § 553(b), (c) et seq. United States v. Picciotto, 850 F.2d 345, 346 (D.C. Cir. 1989); Mt. Diablo Hospital District v. Bowen, 860 F. 2d 951, 956-57 (9th Cir. 1988); and Linoz v. Heckler, 800 F.2d 871, 878 (9th Cir. 1986).[5]

Moreover, the directives contained in those letters do not qualify under the APA exceptions for interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice. . . 5 U.S.C. § 553(b) et seq. The Providers argue that interpretive rules are those that

---

[5] Tr. at p. 40.

"clarify or explain existing law or regulations and are by that "non-binding," and do not foreclose alternate courses of action or conclusively affect the rights of private parties." Flagstaff Medical Center Inc. v. Sullivan, 962 F.2d 879, 876 (9th Cir. 1992) and Batterton v. Marshall 648 F.2d 694, 702 (D.C. Cir. 1980). Conversely, substantive rules are those that effect a change of existing law or policy. Powderly v. Schweiker, 704 F.2d 1092 (9th Cir. 1983) and Flagstaff, 962 F.2d at 866.

The Providers contend that because the ILs at issue constituted an entire reimbursement scheme for outpatient dialysis, they amounted to substantive rules under the APA and the controlling case precedent. The limits and requisite justifications were clearly substantive because they affected a provider's ability to seek reimbursement for dialysis services. The Providers also assert that the District Court for the District of Columbia specifically found partially invalid, the 1973 IL, because it amounted to a substantive rule and was not promulgated in accordance with the APA. Schupak v. Mathews, [1976 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 27,987, at 10,004 (D.D.C. Sept. 17, 1976), aff'd unpublished order(D.C. Cir. 1977). Specifically, the court stated that the 1973 IL "directly controls the reimbursement to be paid to dialysis facilities[,] ... is definitive, new, and controlling, and is precisely the sort of regulation required to be imposed only pursuant to the rule making requirements of the APA." Id. The Providers claim that the Schupak court invalidated the very same screens at issue here. As such, the Providers maintain that the provider-based screens, like the non-provider screens, are substantive rules that could only be validly enforced if promulgated in accordance with the notice and comment provisions of the APA.

The Providers also contend that the interim regulation was not meant to remain in effect for ten years. Further, the language of the regulation stated that "rules may be developed for establishing limits on costs and services above which reimbursement shall be made only upon appropriate justification." 38 Fed. Reg. 17,210, 17,211-212 (June 29, 1973), (codified at 42 C.F.R. § 405.402(g) et seq. Moreover, the regulation authorized the issuance of "temporary instructions modifying the provisions of this subpart ... in order to implement [the ESRD Program]." Id. (emphasis added). Therefore, the Providers assert that the regulation was temporary by its own terms and required that rules be developed for formulating ESRD reimbursement limits. Next, the Providers contend that the regulation was without statutory authority when promulgated and expressly invalid as of October 1978. First, the statute did not authorize the Secretary to promulgate a regulation allowing for temporary screens. Second, Congress repealed section 2991 in 1978, thust removing the only statutory authority for the 1973 regulation. See 1978 Act, §§ I (b)(1), 6. Further, the 1978 amendment expressly mandated new regulations to implement the ESRD reimbursement mechanism. Therefore, if the Board concludes that the 1973 interim regulation provides support for the promulgation of the ESRD screens, without following the notice and comment provisions of the APA, the 1973 regulation could not do so after Congress repealed the only statutory basis for the 1973 regulation. See Bowen v. Georgetown University Hospital, 109 S. Ct. 468, 471 (1988). Accordingly, the Providers claim that there is no statutory authority for the interim regulation after 1978 and therefore, the Board must rule its application to the Providers, unlawful.

Finally, the Providers contend that the pre-composite rate ESRD screens which were established violated the substantive requirements of the APA. See 5 U.S.C §706 (2)(A); See also Motor Vehicles Mfrs. Assn. v. State Farm Mut. Auto Ins. Co. 103 S. Ct. 2856 (1983). The APA requires that an agency must "examine the relevant data and articulate a satisfactory explanation for its action . . . ." Id. at 2866. To this end, the Providers argue that during the ten years that the pre-composite rate ESRD screens were in effect, HCFA provided no information regarding the basis for its methodology for the establishment of the screens. Moreover, the District Court for the District of Columbia findings concerning the ILs at issue here clearly support its position. Specifically, the court found that the ESRD screens were adopted without publication or explanation" ... [and] "there is no evidence in the record of the basis for or methodology by which HCFA derived the $138 screen." Cleveland Clinic Foundation v. Sullivan, [1992-1 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 39,519 and ¶ 27,487-48 (D.D.C. July 30, 1991) (emphasis added). Moreover, with respect to the appeal at issue and in the companion cases, the Providers specifically sought the information through a FOIA request. However, HCFA responded by stating that it did not have any information responsive to the Providers' request. Hence, the Providers assert that HCFA's total lack of documentation supporting the screens, and its total disregard of Congressional mandate, clearly requires that the screens be invalidated as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706 (A).

INTERMEDIARY'S CONTENTIONS:

The Intermediary contends that the Board should, on its own motion, submit this appeal for expedited judicial review ("EJR") because it does not have the authority under 42 C.F.R. § 405.1867 to review the Providers' challenge to HCFA's policy, procedure and established practices as they relate to the ESRD pre-composite rate. Alternatively, the Intermediary asserts that, in the event the Board accepts jurisdiction over this appeal, HCFA had the requisite statutory and regulatory authority to implement the ESRD screens at issue. Thereby, HCFA did not violate either the substantive or procedural requirements of the APA.[6]

The Intermediary contends that the Board must dismiss this appeal because it lacks jurisdiction to review HCFA's policy, procedure, and established practices, pursuant to the governing Medicare regulations. The Intermediary asserts that the regulation specifically requires that the "Board shall afford great weight to interpretive rules, general statement of policy, and rules of agency organization, procedure, or practice established by HCFA." 42 C.F.R. § 405.1867 (emphasis added). Accordingly,

---

[6] The Board finds that the position paper filed by the local plan is for the most part indecipherable. As such, the Board has to the best of its ability, gleaned the Intermediary's position from that filing and from the oral argument presented by Intermediary's counsel.

the Board must either dismiss the Providers' appeal or issue an order for EJR under the regulation at 42 C.F.R. 405.1842(c) et seq.[7]

The Intermediary contends that the Secretary had the statutory authority to fix the ESRD rate under the Social Security Act Amendments of 1972, Pub. L. No. 92-603, 2991, 1972 U. S.C.C.A.N. (Stat) 1463, 1713 (codified at 42 U.S. C. § 426(e), (f), and (g)). Specifically the amendment authorizes the Secretary to "limit reimbursement under Medicare for kidney transplant and dialysis to kidney disease treatment centers which meet such requirements as he or she may by regulation prescribe. . ." 42 U.S.C. § 426 (g) (emphasis added). The Intermediary contends that Congress' use of the phrase "may by regulation" rather than the term "shall," declares the Secretary's clear authority to limit reimbursement for ESRD services.

The Intermediary contends that the Secretary's actions in not promulgating final regulations until 1983 did not breach the provisions of the APA. The interim regulations clearly stated that HCFA had no experience with the delivery of ESRD services. Moreover, the regulations specifically described the services as very complex. Accordingly, the Intermediary maintains that an interim period for the regulation at issue was appropriate under the circumstances.

The Intermediary also claims that during the interim period, limits on reimbursement would be applied to "amounts and services covered beyond which payment will be made, i.e., will be considered reasonable and necessary, only if adequate justification is provided." 38 Fed. Reg. 17,210 (June 29, 1973), (codified at 42 C.F.R. § 405.402 (emphasis added). Therefore, if the Providers were dissatisfied with its reimbursement, they should have availed themselves of the exception process to justify the costs of furnishing ESRD services.

The Intermediary contends that the methodology of communicating the establishment of the ESRD rates was pursuant to statute, at the option of the Secretary. The Intermediary claims that communicating the rates through Intermediary Letters was appropriate and the Providers' challenge of the same based on both procedural and substantive provisions of the APA is without support. The regulation stipulated the method of reimbursement through the interim period with the exception for providers whose costs exceeded the limit. Accordingly, the Intermediary maintains that setting the rates through Intermediary Letter did not violate the APA.

---

[7] The local Intermediary who prepared and filed the position paper in this appeal urged the Board to EJR this appeal on its own motion pursuant to 42 C.F.R. § 405.1842(c). However, during the hearing, Intermediary's counsel made its own motion that the Board order the EJR of this issue in the appeal here as well as the companion cases, claiming that the Board is without the authority to decipher the propriety of the ESRD screens at issue. Tr. at 26.

With respect to the Providers' challenge premised on the notice and comment provisions of the APA, the Intermediary asserts that those provisions are inapplicable. The Intermediary Letters at issue clearly come under the exceptions for "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. §553(b)(3)(A) et seq (emphasis added). As such, publishing the pre-composite rates through the subject Intermediary Letters fell within the notice and comment provisions of the regulations.

CITATION OF LAW, REGULATIONS & PROGRAM INSTRUCTIONS:

1. Law:

Title XVIII of the Social Security Act:

§ 1861	-	Miscellanous Provisions
§ 1861 (v)	-	Reasonable Cost
5 U.S.C. §553 et seq.	-	Administrative Procedure Act
5 U.S.C § 706 et seq.	-	Scope of Review
42 U.S.C. § 426(e), (f) and (g)	-	ESRD Coverage/ Social Security Amendments of 1972
42 U.S.C. § 1395oo	-	Provider Reimbursement Review Board
42 U.S.C.§ 1395rr et seq.	-	ESRD Program Improvements
42 U.S.C.§ 1395x(v) et seq.	-	Reasonable Costs

2. Other Statutes:

Public Law 92-603 (1972) et seq.

Public Law 95-292 (1978)

3. Regulations - 42 C.F.R.:

§ 405.402 et seq.	-	Cost Reimbursement; General

§ 405.451	-	Criteria for Determination of Reasonable Charges for Items and Services Furnished by Independent ESRD Facility before August 1, 1983
§§ 405.1835-.1841	-	Board Jurisdiction
§ 405.1842 et seq.	-	Expedited Judicial Review
§ 405.1867	-	Sources of Board Authority
§ 413.9	-	Cost Related to Patient Care

4. Federal Register:

38 Fed. Reg. 17,210, 17,211 -212 (June 29, 1973)

48 Fed. Reg. 21,254 (May 11, 1983)

5. Part A Intermediary Letters:

73-25 Chronic Renal Disease - Interim Policies/Procedures

73-24 Chronic Renal Disease - Facility Reimbursement

74-26 Chronic Renal Disaease - Reimbursement Screen

75-19 Chronic Renal Disease - Provider Reimbursement

77-35 Renal Disease Screens - Reimbursement for Outpatient Dialysis

78-9 Submission of Renal Dialysis Facility Cost and Statistical Information

82-1 End Stage Renal Disease Facilities - Documentation for Exception to Payment Screens

6. Part B Intermediary Letters:

73-22 Chronic Renal Disease - Interim Policies/Procedures

74-24 Chronic Renal Disease - Reimbursement Screens

7. Case Law:

Batterton v. Marshall, 648 F. 2d 694 (D.C. Cir. 1980).

Bowen v. Georgetown University Hospital, 109 S. Ct. 468 (1988).

Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 104 S. Ct. 2778 (1984).

Cleveland Clinic Foundation v. Sullivan, [1992-1 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 39,519 (D.D.C. July 30, 1991).

Flagstaff Medical Center, Inc. v. Sullivan, 962 F. 2d 879 (9th Cir 1992).

Linoz v. Heckler, 800 F. 2d 871 (9th Cir. 1986).

Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co., 103 S. Ct. 2856 (1983).

Mt. Diablo Hospital District v. Bowen 860 F. 2d 951 (9th Cir. 1988),

Powderly v. Schweiker 704 F. 2d 1092 (9th Cir. 1983).

Schupak v.Mathews, [1976 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 27,987 (D.D.C. September 17, 1976), aff'd unpublished order (D.C. Cir. 1977).

United States v. Picciotto, 850 F.2d 345, 346 (D.C. Cir. 1989).

FINDINGS OF FACT, CONCLUSIONS OF LAW AND DISCUSSION:

The Board, after consideration of the facts, parties' contentions, evidence presented, and testimony elicited at the hearing, finds and concludes as follows:

The Board concludes that it has the authority pursuant to Medicare statute and regulation to adjudicate the validity of the ESRD screens which were instituted through ILs. Further, the Board finds that the ESRD screens were established without following the required notice and comment provisions of the APA. The Board also concludes that because the creation of reimbursement limits is not, by definition, an interpretive rule under the relevant case authority, the ILs establishing the screens do not fall within the APA exceptions. Therefore, the Secretary was required to follow rule making procedures. 5 U.S.C. § 553(b)(A) et seq. The Board rules that there is substantial evidence in the record to conclude that the screens were established in an arbitrary and capricious manner and thus are violative of the substantive requirements of the APA. 5 U. S.C. § 706 (2)(A). Accordingly, the Board finds that the ESRD screens are invalid, and as such, may not be applied to the Providers.

Legislative History of the ESRD Pre-Composite Rate Screens:

During the cost reporting years at issue, the Providers were reimbursed by Medicare for the "reasonable costs" incurred for the provision of services to Medicare beneficiaries. Title XVIII of the Social Security Act, section 1861, codified at 42 U.S.C. § 1395x(v)(1)(A) et seq. The regulations implementing this statute appear at 42 C.F.R. § 405.451 (redesignated at 42 C.F.R. § 413.9).

In October 1972, Congress established the ESRD program by extending Medicare coverage to insured individuals who required hemodialysis or renal transplantation for this disease. Social Security Act Amendments of 1972, Pub. L. No. 92-603, § 2991, 1972 U.S.C.C.A.N. (Stat.) 1463, 1713 (codified at 42 U.S.C. § 426(e), (f), and (g)). The pertinent section of the statute for purposes of this appeal was to be in effect on July 1, 1973 and read, "the Secretary [of Health and Human Services ("Secretary") is authorized to limit reimbursement under Medicare for kidney transplant and dialysis to kidney disease treatment centers that meet such requirements as he may by regulation prescribe. . . ." 42 U.S.C. § 426(e), (f), and (g).

The implementing regulations for the ESRD program were designated as "interim" regulations and implemented without notice and comment. 38 Fed. Reg. 17,210 (June 29, 1973) to be codified at 20 C.F.R. § 405.402(g). In pertinent part the preamble to that regulation reads:

> [t]he legislation authorizes the Secretary to limit reimbursement as he may prescribe by regulation. In view of the new issues that stem from the virtually universal coverage of a very complex service, the absence of prior experience, and possible precedents that the regulation may establish, final decisions on Medicare payment and facility qualification policies will require careful study and reevaluation based on operating experience. Operations on July 1, 1973 are to be based on interim regulations.... In addition, interim reimbursement levels and mechanisms to be employed should not be construed to reflect the final policies which will be adopted and which are expected to contain additional features providing incentives for effective and efficient performance. During the interim period, limits will be applied to reimbursement amounts and services covered beyond which payment will be made, i.e., will be considered reasonable and necessary, only if adequate justification is provided....

38 Fed. Reg. 17,210 (June 29, 1973).

Next, the Bureau of Health Insurance ("BHI"), predecessor to the Health Care Financing Administration ("HCFA') issued Intermediary Letters ("IL") stating the interim policies and procedures concerning chronic renal disease.[8] The letters issued on June 29, 1973, were effective July 1, 1973,

---

[8] Intermediary Letters are guidelines for fiscal intermediaries that govern reimbursement practices

and established specific dollar limits of $150 and $145[9] to all provider and non-provider facilities rendering ESRD services. See IL Part A 73-25 and Part B 73-22. A year later, another IL was issued altering the reimbursement rate to $138 per treatment. This is the rate in dispute in this appeal. See IL Part A 74-26 and Part B 74-24 (August 1974). The interim reimbursement screens remained in effect until the establishment of the composite rate reimbursement system in August 1983.[10] 48 Fed. Reg. 21,254 (May 11, 1983).

Litigation ensued over the subject ESRD screens, specifically the Schupak v. Matthews decision wherein the federal District Court for the District of Columbia invalidated the 1973 IL in an action brought by a non-provider. First the court found that the ESRD reimbursement policies set forth in the 1973 IL constituted substantive rules not promulgated in accordance with the Administrative Procedure Act ("APA"). The court went on to invalidate the 1973 IL "insofar as it imposes a formula for the calculation of an estimated customary charge for non-providers under the chronic renal disease Medicare program." Schupak v. Matthews, [1976 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 27,987, at 10,007 (D.D.C. Sept. 17, 1976), aff'd unpublished order (D.C. Cir. 1977).

Fifteen years later, the same court addressed the validity of the ESRD screens in Cleveland Clinic Found, v. Sullivan, [1992-1 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 39,519 (D.D.C. July 30, 1991) ("Cleveland"). The district court noted that the subject screens were adopted without publication or explanation" ... [and] there is no evidence in the record of the basis for or methodology by which the Secretary derived the $ 138.00 screen in 1973." Id. at ¶27,487. The court, after noting the lack of substantive justification for the screens, set aside the HCFA Administrator's ruling and remanded to the Secretary "in order that he may supplement the administrative record to explain the basis and justification for the $138.00 screen." Id. at ¶27,488.

On June 13, 1978, Congress enacted the End Stage Renal Disease Program Improvements. Pub. L. No. 95-292, 1978 U.S.C.C.A.N., 92, Stat. 307, codified at 42 U.S.C. § 426-1, 1395rr. This amendment expressly repealed section 2991 and mandated that HCFA determine the amount of payment for ESRD services under Part A of the Medicare program "in accordance with section 1861(v). This section requires regulations to establish the methods used in setting limits on.... costs ... of specific items or services to be recognized as reasonable....." 42 U.S.C. § 1395x(v)(1)(A) et seq. With respect to Part B services, the 1978 Act required HCFA to establish regulations for payments to providers for ESRD services, which set forth:

---

[9] $145 was paid when the laboratory was separately billed.

[10] See Provider Exhibit 5 -- Part A IL 75-19 (May 1, 1975) extending interim ESRD screens to July 1, 1976 and Provider Exhibit 6 -- Part A IL 77-35 (November 1977) extending ESRD screens indefinitely

> methods and procedures to: (1) determine the costs incurred by providers of services and renal dialysis facilities in furnishing covered services to individuals determined to have end-stage renal disease, and (2) determine, on a cost-related basis or other economical and equitable basis (including any amount authorized under section 1861 (v)), the amounts of payments to be made under Part B services furnished by such providers and facilities to such individuals.

1978 Act, § 2, codified at 42 U.S.C. § 1395rr (b)(2)(B) et seq.

With respect to the process for requesting an exception from the pre-composite rate ESRD screens, the Secretary's instructions were contained in ILs. Specifically, IL 78-9 and IL 82-1, required providers to submit an ESRD cost questionnaire with its annual cost report. If a provider incurred cost above the ESRD screens, the provider was responsible for submitting documentation to support the reasonableness of the additional reimbursement. The letters instructed the intermediaries to examine the reasonableness of the costs as compared to peer group facilities.

Discussion:

The Board concludes that it has jurisdiction to decipher the validity of the subject ESRD screens pursuant to the statute at 42 U.S.C. § 1395oo and the regulations at 42 C.F.R. §§ 405.1835-1841. Specifically, the regulation setting forth the sources of the Board's authority states, that "the Board must comply with all the provisions of title XVIII of the Act and regulations issued thereunder, as well as HCFA Rulings.... The Board shall afford great weight to interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by HCFA." 42 C.F.R. §405.1867. The Board finds that the ILs at issue are neither statutes nor regulations, and as such, an assessment of their validity here is appropriate under the circumstances presented. Accordingly, the Board will not expedite this issue for judicial review under the procedures set out in 42 C.F.R. § 405.1842(a) et seq.

The Board concludes that the ESRD screens were established without following the required notice and comment provisions of the APA. 5 U.S.C. § 553(b) and (c) et seq. A substantive rule implemented without following the procedural rule making requirements of the APA is invalid. Mt. Diablo Hospital District v. Bowen, 860 F.2d 951, 956-57 (9th Cir. 1988). The Board finds that the screens instituted through ILs constituted the entire reimbursement scheme for dialysis services for a ten year period. Further, the screens cannot be characterized as "interpretive" rules which are excepted from the procedural rule making requirements of the APA, because interpretive rules only include “those which merely clarify or explain existing law or regulations. .”
Powderly v. Schweiker, 704 F.2d 1092, 1098 (9th Cir. 1983).

The Board opines that its finding that the screens were implemented by substantive rule rather than an "interpretive" rule is supported by the federal district court's ruling in Schupak. The district court held that a portion of the 1973 IL at issue here was invalid as a substantive rule not promulgated in accordance with the APA. See Schupak at 10,004. Specifically, the court stated, that the 1973 IL "directly controls the

reimbursement to be paid to dialysis facilities, . . . has a substantial impact on the rights of those facilities [,] ... is definitive, new . and controlling, and is precisely the sort of regulation required to be imposed only pursuant to the rule making requirements of the APA." Id. Accordingly, the Board concludes that the screens were established in violation of the procedural requirements of the APA and are invalid.

The Board also agrees with the Providers' observation that the Secretary's 1973 interim regulation was not intended to establish cost limitations for a ten year period without going through the formal rule making process. That regulation stated that "rules may be developed for establishing limits on costs and services above which reimbursement shall be made only upon appropriate justification." 38 Fed. Reg. 17,210, 17,211-212, June 29, 1973 (later codified at 20 C.F.R. § 405.402(g) and subsequently redesignated to 42 C.F.R. § 405.402(g)). Further, the language of the interim regulation only authorized the issuance of "temporary instructions" to implement section 2991 of the Act. Id. The Board opines that ten years is an excessive amount of time to impose a reimbursement limitation without formal rule making. Moreover, the Board concludes that the screens implemented through the Intermediary Letters at issue were temporary in nature and scope. As such, the application of the screens to the Provider's ESRD costs, eight, nine, and ten years after the screens were established was improper.

The next inquiry for the Board is whether the subject ESRD screens were established in violation of the substantive requirements of the APA. The APA declares unlawful any agency action which is "arbitrary capricious, an abuse of discretion, or otherwise not in accordance with the law. . ."
5 U.S.C. § 706(2)(A); see also Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.
103 S. Ct. 2856, 2865 (1983). Further, the agency must "examine the relevant data and articulate a satisfactory explanation for its action. . . ." Id. at 2866. Moreover, if Congress has "explicitly left a gap for the agency to fill," the agency's regulations, pursuant to the gap, are not given controlling weight if "they are arbitrary, capricious, or manifestly contrary to the statute." Chevron U.S.A, Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 867 (1984).

The Board finds that it was presented with persuasive testimonial evidence from the Providers' expert witness, Dr. Richard Rettig, concerning the implementation of the ESRD program and the establishment of the cost limitations at issue. Dr. Rettig demonstrated his extensive knowledge of the ESRD program[11] and authored a report entitled "Implementing the End-Stage Disease Program of Medicare" which was sponsored by HCFA.[12] This report covers the legislative history of the Kidney Entitlement Amendment, of the Social Security Amendments of 1972, section 2991,[13] and was used to establish the interim regulations.[14]

---

[11] See generally tr. at 30-81.

[12] Tr. at 31 and Provider Exhibit 71

[13] Tr. at 32 and Provider Exhibit 71.

[14] Id.

The Board found convincing Dr. Rettig's confirmation of the findings of the federal district court in Cleveland, that there was no evidence of the basis for the methodology by which HCFA derived the 1973 screens.[15] Further, he concluded that the data used to establish the screens was "sketchy" and "skimpy."[16] The Board also observed that HCFA did not, and could not, produce the data used to determine the screen amount even though a FOIA request was made.[17] This factor together with the circumstances in the Cleveland case clearly support the Board's conclusion that the data used was insufficient to set the screens and limit ESRD reimbursement for a ten year period.[18] Accordingly, the Board finds that establishment of the screens, which amounted to a limit on reimbursement for ESRD services for a ten year period, is arbitrary, capricious, and not in accordance with the law. As such, the screens. violate the substantive directives of the APA 5 U.S.C. § 706 (2)(A) and Motor Vehicle Mfrs, Ass'n v. State Farm Mut, Auto. Ins, Co., 103 S. Ct. 2856, 2865 (1983).

Therefore, the Board concludes that the subject ESRD screens are invalid, and as such, may not be applied to the Providers. The Board reverses HCFA's determination.

With respect to the Providers' argument that there was no statutory basis for the interim regulation, the Board disagrees. Under the dictates of Chevron, the Board concludes that Congress clearly intended the Secretary to implement the ESRD program, including the gathering of data to develop a reimbursement scheme for the program. The interim regulations accomplished that purpose. However, as the Board has already ruled, an interim period of ten years is inappropriate under any standard. The Board also concludes that it does not need to reach the issue of whether the statutory authority for the regulation was repealed. The Providers argue that the referenced repeal invalidated the interim regulation the Secretary relied upon to establish the screens. However, the Board concludes that the screens were simply implemented in violation of both the procedural and substantive dictates of the APA. Accordingly, their application to the Providers was improper.

DECISION AND ORDER:

The Board finds that the pre-composite rate screens established through the 1973 intermediary letter violate the procedural and substantive requirements of the APA. Accordingly, the Board concludes that HCFA's

---

[15] Tr. at 52.

[16] Tr. at 42 and 46.

[17] See Provider Exhibit 36.

[18] With respect to the Cleveland case, the Board observes that if the data had been produced as required by the court order, then it should have been available for production at the time the FOIA request was made. Hence, even though there was no further proceedings in Cleveland an inference may be drawn that data does not exist to support the establishment of the screens.

application of the screens to the Providers' ESRD costs was improper, and, therefore, the Providers should be reimbursed its reasonable costs.

Board Members Participating:

Irvin W. Kues
James G. Sleep
Henry C. Wessman, Esquire
Martin W. Hoover, Esquire
Charles R. Barker

Date of Decision: September 21, 1999

For The Board

Irvin W. Kues
Chairman